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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,846	09/17/2001	Y. Tom Tang	PF-0556-1 DIV	9384
27904	7590	03/04/2004		
INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304			EXAMINER	LI, RUIXIANG
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/954,846	TANG ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 22 December 2003.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 3-9, 11-17, 19, 20, 24-28 and 46 is/are pending in the application.

4a) Of the above claim(s) 8, 13-17, 19, 20 and 24-28 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 3, 6, 7, 9, 11, and 12 is/are rejected.

7) Claim(s) 4,5 and 46 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### **I. Status of Application, Amendments, and/or Claims**

The amendment filed on December 22, 2003 has been entered in full. Claims 3, 4, and 9 have been amended. Claims 3-9, 11-17, 19, 20, 24-28, and 46 are pending. Claims 3-7, 9, 11, 12, and 46 are under consideration.

It is further noted that claim 1 is listed as "canceled" in the pending claims, but stated that the claim is amended at page 7 of Applicants remarks filed on December 22, 2003. Clarification is requested.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Priority**

In view of Applicants' argument about utility of the present invention, the Examiner agrees that the claimed subject matter is entitled to the priority date, June 30, 1998, which is the filing date of 09/107, 248.

### **III. Withdrawn Objections and/or Rejections**

The rejection of claims 3-7, 9, 11, 12, and 46 under 35 U.S.C. §101, as set forth at pages 3-5 of the previous office action (Paper No. 8, September 24, 2003), has been withdrawn in view of Applicants' argument that the polypeptide of SEQ ID NO: 2 has thioredoxin activity.

The rejection of claims 3-7, 9, 11, 12, and 46 under 35 U.S.C. §112, 1<sup>st</sup> paragraph due to lack of utility, as set forth at the second paragraph of page 5 of the

previous office action (Paper No. 8, September 24, 2003), has been withdrawn in view of Applicants' argument.

The rejection of claims 11 and 46 under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, as set forth at page 9 of the previous office action (Paper No. 8, September 24, 2003), has been withdrawn in view of Applicants' argument.

The rejection of claims 3, 4, 6, 7, 9, 11, and 12 under 35 U.S.C. 102(b) as being anticipated by Kato et al. (WO200005376-A2, February 3, 2000), as set forth at page 10 of the previous office action (Paper No. 8, September 24, 2003), has been withdrawn in view of Applicants' argument about the utility of the presently claimed invention and the determination that the claimed subject matter is entitled to the priority date, June 30, 1998, the filing date of 09/107, 248.

The objection of claims 3 and 4 for being dependent on unelected claims has been withdrawn in view of Applicants' amendment to the claims.

#### **IV. Claim Rejections under 35 USC § 112, 1<sup>st</sup> paragraph (Scope of Enablement)**

The rejection of claims 3, 6, 7, 9, 11, and 12 under 35 USC § 112, 1<sup>st</sup> paragraph (Scope of Enablement), as set forth at pages 5-7 of the previous office action (Paper No. 8, September 24, 2003), is maintained because Applicants have not addressed the rejection of scope of enablement.

In view of Applicants' amendment to the claims, the rejection related to the scope of enablement is further clarified below.

(1) Claim 3 (d) recites an immunogenic fragment of a polypeptide having an amino acid sequence of SEQ ID NO: 2. Since an antibody produced by an

immunogenic fragment of SEQ ID NO: 2 does not necessarily bind to the protein of SEQ ID NO: 2 itself, the claim encompasses a large number of inoperative nucleic acids, which an artisan would not know how to use. It is suggested that a specific functional limitation, such as "which is useful for production of an antibody that binds to the polypeptide of SEQ ID NO: 2", be added to limit the scope of the invention. Claims 6, 7, and 9 depend from claim 3.

(2) Claim 11(b) recites a polynucleotide comprising a naturally occurring polynucleotide sequence at least 90% identical to SEQ ID NO: 4. Since the claim does not require a functional limitation, such as, encoding a protein having thioredoxin activity and the specification fails to provide sufficient directions to guide an artisan to use those variants that do not have the same functions as SEQ ID NO: 4, an artisan would not be able to use the claimed genus of nucleic acids without undue experimentation.

(3). Claim 12 recites an isolated polynucleotide comprising at least 60 contiguous nucleotides of SEQ ID NO: 4 or its natural variants. However, other than the polynucleotide sequence of SEQ ID NO: 4 encoding the polypeptide of SEQ ID NO: 2, the specification fails to provide sufficient guidance, information or working examples regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. If Applicants intend to claim the use of such nucleic acids as probes or primers, they should clearly indicate so and the binding target of the probes or primers; if Applicants intend to claim such nucleic acids as protein encoding sequence. They should limit the nucleic acid by indicate the biological function of the protein/fragments encoded by the claimed nucleic acids.

**V. Claim Rejections under 35 USC § 112, 1<sup>st</sup> paragraph (Written Description)**

The rejection of claims 3, 6, 7, 9, 11, and 12 under 35 USC § 112, 1<sup>st</sup> paragraph (Written Description), as set forth at pages 7-9 of the previous office action (Paper No. 8, September 24, 2003), is maintained.

Applicants argue, citing case law and the PTO's "Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, 1<sup>st</sup> paragraph", that one of ordinary skill in the art would recognize naturally-occurring variants of SEQ ID NO: 4 having 90% sequence identity to SEQ ID NO: 4, given SEQ ID NO: 4. Accordingly, the specification provides an adequate written description of the recited polynucleotides sequences (bottom of page 29 to top of page 31).

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, while claim 3(b), (c) has been amended to recite a functional limitation, claim 11 (b) does not require any biological activity, such as, "encoding a polypeptide having thioredoxin activity". Thus, with a mere recitation of sequence identity to SEQ ID NO: 4, claim 11 (b) fails to satisfy the description requirement; a functional limitation for claim 11(b) is required.

Secondly, the specification fails to disclose functional natural variants with *at least 90% identical to SEQ ID NO: 4*. What is disclosed is a mere statement that the invention encompasses a variant of a polynucleotides sequence encoding TRXP. There is no actual description of the nucleotide sequence of the variants of SEQ ID NO: 4 with *at least 90% identical to SEQ ID NO: 4*. Even if the specification had disclosed a number of variants with at least 90% identical to SEQ ID NO: 4, the specification would still have not been found to provide sufficient description for the naturally occurring

variants because it fails to teach how to distinguish a naturally occurring amino acid sequence from a non-naturally occurring one. Thus, in this respect, it is suggested that "a naturally occurring amino acid sequence" be replaced by "an amino acid sequence" to overcome the rejection of claim 3(b) and claim 11 (b).

It is noted that the rejection of claim 3(d) and claim 12 under 35 USC § 112, 1<sup>st</sup> paragraph (Written Description) also remains. Applicants have not specifically address these issues. It is suggested that a specific functional limitation be added to these claims to overcome the.

## **VI. Claim Objections**

(1) The objection of claim 9 for being dependent on unelected claim 1 is maintained. Applicants have not fully amended the claim yet.

(2) The amended claim 9 is also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). As written, claim 9 depends upon both claim 1 and 3.

(3) The objection of claim 46 as being a substantial duplicate to claim 5 remains. Applicants have not amended the claims. It is also suggested that "A polynucleotide" be replaced by "An isolated polynucleotides" in claim 46.

## **VII. Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a

possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Ruixiang Li  
Examiner  
February 24, 2004

*Gary A. Kunz*  
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SUPERVISORY PATENT EXAMINER  
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